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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,357	06/02/2006	Raymond Campagnolo	291448US6X PCT	4580
22850	7590	01/03/2011	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			MELLON, DAVID C	
			ART UNIT	PAPER NUMBER
			1777	
			NOTIFICATION DATE	DELIVERY MODE
			01/03/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/581,357	Applicant(s) CAMPAGNOLO ET AL.	
	Examiner DAVID C. MELLON	Art Unit 1777	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37,40-44,48,50,51,53,73 and 74 is/are pending in the application.
- 4a) Of the above claim(s) 48 and 50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37,40-44,51,53,73 and 74 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20101216</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/16/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 37, 40-44, 51, 53, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Amada et al. (JP 2001-221799 as cited on the IDS filed 12/16/2010) and in view of Colin et al. (USP 5,925,573).

Regarding claims 37, 51, 73-74, Amada et al. discloses a method for dividing an analyte present in a solution (title/abstract) in figures 1(a/b) comprising:

Disposing the solution including the analyte fixed to magnetic particles in a first receptacle ([0077-0082] - see in figure 1b the left portion before the split represents the first receptacle portion)

Attracting with a magnetic mechanism the magnetic particles fixed to the analyte to a bottom of the first receptacle and forming an initial residue at the bottom ([0081-0082] - sedimentation)

After forming the initial residue, dividing the residue into a plurality of residues by transporting the residue through channels to second receptacles (right side on figure 1b) by a magnetic mechanism ([0082-0084]).

Amada is silent as to the use of two separate magnetic mechanisms, one for attraction and one for motion.

Colin et al. discloses a method for dividing an analyte present in solution in a first receptacle (8) into plural second receptacles (17), the analyte fixed on magnetic particles (C4/L1-55 - see discussion of particles with cores), the method (abstract) and in figures 2 and 3 comprising:

- Sedimentation of magnetic particles by a first magnetic mechanism (3, see also C2/L60-65, C8/L20-30, C10/L25-35)
- Formation of a plurality of residues in the second receptacles (C10/L15-30)
- The sedimentation first occurring in the first receptacle (C10/L15-30, see also figures, and also C8/L20-30)
- The first residue is transported by relative displacement of a magnetic field created by a second magnetic means (3 which is a long bar) which is coincident/the same with the first means (C8/L50-65, C2/L60-65)
- The fluid channels area parallel (see figure 3)
- The first residue is single and linear shaped (using magnet 3 it is inherently linear due to the linear magnet shape and would divide the receptacle into two parts)
- The fluid channels are all on the same side of the first residue (see figure 3)

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- The at least first residue is moved to the second receptacles (See figure 3, also see C10/L15-35)
- The channels are capillaries (C10/L45-65)
- The analyte is previously fixed and added to solution in the first receptacle (C4/L1-55).

While Colin et al. does not explicitly disclose all claim limitations within a single embodiment, it would have been obvious to one having ordinary skill in the art to combine the embodiments of figures 2 and 3 to change the magnet system of 3 into a moving bar magnet such as that of figure 2 and also at C2/L60-65 for the purpose of allowing for a maximization of transfer of magnetically susceptible particles due to the fact that the magnet itself is moving and thus a higher amount of material would be drawn than if a distant magnet source were used. Furthermore, it is established that obviousness may be found in a combination of embodiments. See for example *Boston Scientific Scimed Inc. v. Cordis Corp* 89 USPQ2d 1704 in which two side by side stent embodiments were determined by the court to be combinable to render claims obvious.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of Amada to further include the use of two separate magnetic mechanisms as taught by Colin for the purpose of providing for two independant magnetic mechanisms which would allow for a continuous operation utilizing both agglomeration of newly added material and transport of previously added materials. Additionally, a benefit of being able to select different strengths of magnets

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for the task would provide for optimizable separation process by tailoring the magnet strengths to a single task.

Regarding claim 40, Amada discloses in figure 1d the use of parallel channels. Additionally, the channels of figure 1b may be considered to run in the same general direction providing for a parallel flow mechanism.

Regarding claim 41, Amada discloses the use of a single magnet entity as an option for operation.

Regarding claim 42, the residue would either be in a linear shape or it would have been obvious to have formed a linear shape residue in view of using a bar shaped magnet.

Regarding claim 43, each channel is located on the same side of the initial residue in a direction of displacement by the magnetic mechanism (see figure 1b or 1d).

Regarding claim 44, the magnetic mechanism includes a linear magnet that moves relative to the channels.

Regarding claim 53, the residues are all divided into equal quantities which feed into each receptacle (see figure 1b).

4. Claims 37, 40-44, 51, 53, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang et al. (US 2006/0024732) and in view of Colin et al. (USP 5,925,573).

Regarding claims 37, 40-41, 51, and 74, Huang et al. discloses in figure 7 a microchannel array for use with a magnetic microdevice (Abstract) and method of operation comprising:

Disposing a solution including analyte fixed to magnetic particles in a first receptacle ([0139], [0108], [0082], [0083], [0148], and [0144])

Attracting with a first magnetic mechanism, the magnetic particles fixed to the analyte to a bottom of the first receptacle and forming an initial residue at a bottom of the first receptacle ([0139] and [0144] - note Applicant hasn't specified forming the residue on the bottom)

After forming the initial residue at the bottom of the first receptacle, dividing the initial residue into a plurality of residues by transporting the initial residue through channels connecting the first receptacle to a second receptacle ([0139-0140], and [0144], see also channels shown in figure 7).

Huang et al. does not explicitly disclose more than one second receptacle.

Colin et al. discloses a method for dividing an analyte present in solution in a first receptacle (8) into plural second receptacles (17), the analyte fixed on magnetic particles (C4/L1-55 - see discussion of particles with cores), the method (abstract) and in figures 2 and 3 comprising:

- Sedimentation of magnetic particles by a first magnetic mechanism (3, see also C2/L60-65, C8/L20-30, C10/L25-35)
- Formation of a plurality of residues in the second receptacles (C10/L15-30)
- The sedimentation first occurring in the first receptacle (C10/L15-30, see also figures, and also C8/L20-30)

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- The first residue is transported by relative displacement of a magnetic field created by a second magnetic means (3 which is a long bar) which is coincident/the same with the first means (C8/L50-65, C2/L60-65)
- The fluid channels area parallel (see figure 3)
- The first residue is single and linear shaped (using magnet 3 it is inherently linear due to the linear magnet shape and would divide the receptacle into two parts)
- The fluid channels are all on the same side of the first residue (see figure 3)
- The magnet provides orthogonality of projection onto the plane of the displacement as required by claim 45
- The at least first residue is moved to the second receptacles (See figure 3, also see C10/L15-35)
- The channels are capillaries (C10/L45-65)
- The analyte is previously fixed and added to solution in the first receptacle (C4/L1-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the process of Huang such that the microdevices/analyte are received in different individual containers as taught by Colin for the purpose of providing multiple sample outlets such that the organized microdevices of Huang need not be remixed or re-separated after processing.

Huang utilizes magnetic force to move the microdevices and that force is using the same magnet for two operations and further as shown in figure 7 all the channels

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are parallel ([0144] - see first small magnet and second larger magnet which provide two magnetic mechanisms; Applicant has not provided any details of the magnetic mechanism which differentiates them from magnets alone).

Regarding claim 42, the residue would either be in a linear shape or it would have been obvious to have formed a linear shape residue in view of using a bar shaped magnet ([0144] of Huang).

Regarding claim 43, each channel is located on the same side of the initial residue in a direction of displacement by the magnetic mechanism ([0144]).

Regarding claim 44, the magnetic mechanism includes a linear magnet that moves relative to the channels ([0144]).

Regarding claim 53, the residues are all divided into equal quantities which feed into each receptacle (Huang [0144], [0165]).

Response to Arguments

5. Applicant's arguments filed 12/16/2010 have been fully considered but they are not persuasive.

- Applicant alleges Huang fails to disclose formation of a residue.

This is not persuasive. A residue is something that remains. Accordingly because Huang removes microdiscs in a liquid, Huang provides for a residue formation. See Huang at [0167] for example.

- Applicant alleges Huang fails to provide a first and second mechanism wherein the second mechanism provides for the transport mechanism.

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This is not persuasive. See Huang at [0144] with a first small magnet and a second large magnet and the relevant description therein.

6. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID C. MELLON whose telephone number is (571)270-7074. The examiner can normally be reached on Monday through Thursday 9:00am-5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571) 272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Tony G Soohoo/
Primary Examiner, Art Unit 1774

/D. C. M./
Examiner, Art Unit 1777